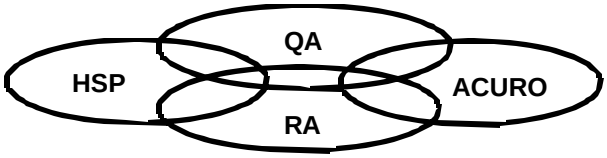
September 2004 FINAL ISSUE

RCQ REVIEW

Newsletter of the Office of Regulatory Compliance and Quality
United States Army Medical Research Materiel Command

Office of Regulatory Compliance and Quality



REALIGNMEMT OF THE FUNCTIONS OF THE OFFICE OF REGULATORY COMPLIANCE AND QUALITY

INSIDE THIS ISSUE:

Message from the DRCQ	1
Annual PRIM&R and ARENA Highlights	2
Unanticipated Problems Involving Risk to Subjects & Others	3
Kathie Mantine: RA Certification	5
What is a 510(k) application?	5
You Think You Know How to Audit?	6
New Additions to ACURO	8
CBRNE Biomedical Research Short Course	8
FY03 Data Call on the Use of Lab Animals	9
RCQ Hails and Farewells	9
Around the Command	9
Helpful Links	10

Message from the Deputy, RCQ This final issue of the RCQ Review announces the much awaited realignment of RCQ functions. In January 2004, MG Martinez-Lopez established a USAMRMC Re-engineering Task Force to identify, improve and standardize the structure, function and processes required to conduct FDA-regulated research. In May 2004, our Task Force proposed a realigned USAMRMC Headquarters regulatory organizational structure and revised business processes to better meet the TSG's responsibilities as a sponsor of research to develop FDA-regulated medical products. Based on the changes recommended by the Task Force, our Commanding General approved the realignment of the Office of Regulatory Compliance and Quality (RCQ) functions and assets. Effective 1 October 2004 the Office of the Deputy RCQ will realign as follows:

The Office of Research Protections is established to oversee Human Subjects Protection and Animal Care and Use Review. The Deputy position from the Office of Regulatory Compliance and Quality will become the Deputy, Office of Research Protections. The Deputy, Office of Research Protections maintains the same organizational placement as the former D, RCQ.

The mission and personnel of the **Regulatory Affairs Branch of RCQ will be transferred the U.S. Army Medical Materiel Development Activity (USAMMDA)**. The Chief, Regulatory Affairs Branch, USAMMDA will report to the Commander, USAMMDA (TSG's Sponsor Representative for FDA activities).

The mission and personnel of the Quality Assurance Branch will be transferred to the newly created HQ USAMRMC Quality Management Office. The Chief of the Quality Management Office will report to the Deputy Commander, USAMRMC.

HSP

HUMAN SUBJECTS PROTECTION

ANNUAL MEETINGS OF PRIM&R AND ARENA HIGHLIGHTS

The annual PRIM&R (Public Responsibility in Medicine and Research) and ARENA (Applied Research Ethics National Association) human subjects protection meetings were held in early December in Washington, D.C., with an overall theme of "Reclaiming the Belmont Principles for Human Research Protections: Looking Back to Move Forward." This article summarizes some highlights of the conference .

Pre-conference Training

During a pre-conference training session for investigators, some major Institutional Review Board (IRB) challenges were identified, including management of multi-site studies, education of study staff, and the need for IRB's to comply with unique requirements of sponsors. Regarding multi-site studies, there is a need for clarification and understanding of the logistics of multi-site processes, improved methods for demonstrating concurrence between sites, establishment of processes for complying with adverse event (AE) reporting regulations, clarification of the roles of sub-investigators versus Principal Investigator's (PI's), and general management of workload and site interrelationships. The use of core protocols with site-specific addendums for other study sites was discussed as one solution, which is an approach that has been used successfully by the Human Subjects Research Review Board (HSRRB). Educational concerns discussed included the need to train PI's and other study staff, with no consensus regarding who needs to be trained, what training should be required for different types of study staff (investigators versus coordinators etc.), and what continuing education requirements should be established. Site-specific training was considered important and some universities devote a whole day of Good Clinical Practice (GCP) training to "local" requirements of their IRB. There is a great need to educate IRB's and PI's regarding the unique regulatory requirements and preferences of certain types of sponsors (such as pharmaceutical companies and government agencies). Web sites and newsletters are considered helpful mechanisms for providing training and updates at many institutions. The HSRRB maintains a web site at https://mrmc-www.army.mil/, which includes links to our guidelines for protocol development, a consent form template, checklists, forms, and applicable regulations.

Government/Regulatory Update

The location of the conference this year afforded RCQ staff and many other federal workers an unprecedented opportunity to attend the meeting, which normally alternates between Boston and San Diego. One of the highlights was a "Meet the Feds" session, at which government workers from different agencies involved in human subjects research answered questions from the audience. This session also included a discussion by the chair of the Secretary's Advisory Committee on Human Research Protections (SACHRP), who emphasized a continued commitment to protecting subjects' rights but also noted the importance of advancing science in a timely manner. During this and other sessions, the new director of the Office for Human Research Protection (OHRP) discussed his agency's vision for the future, indicating plans to concentrate his agency's limited resources on areas that he feels will have the most impact in terms of human subjects protection. This was a common theme throughout many presentations this year, which emphasized the importance of meeting the intent of human subjects protection regulations, rather than "dotting i's and crossing t's." There was a clear desire to simplify procedures where possible and focus on what's really critical, versus what's "nice to have."

International Research

There was a noticeable increase in the international presence at this year's conference. The importance of extending the concept of "respect for persons" to international IRB's was a significant point made during one session, which emphasized that there are very capable local IRB's in other countries who are more knowledgeable about local customs and practices than IRB members in the U.S. Also, we need to be aware of different regulatory requirements in other countries (e.g, different requirements for continuing review and

(Continued on page 3)

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adverse event reporting). The International Ethical Guidelines for Biomedical Research Involving Human Subjects is considered a valuable resource for international studies and is available on the web at http://www.cioms.ch/frame_guidelines_nov_2002.htm.

Miscellaneous Topics

Another session of interest discussed outcomes of the National Institutes of Health (NIH) Human Subjects Research Enhancement Awards (HSREA), which are grants awarded by NIH to strengthen oversight of human subjects research and support development of new or existing human subject advocacy programs. These funds have been used successfully for the development of databases and web-based information to improve operation of IRB's, development of a consortium of IRB's (which share PI's in the same area), development of common/standardized forms, and performance of Quality Assurance (QA) type research on the effectiveness of different IRB systems. Additional information regarding this NIH program can be obtained at http://grants2.nih.gov/grants/policy/hsrea/hsrea.htm.

The importance of a good scientific review was highlighted during a controversial discussion on adult respiratory distress syndrome (ARDS) research. Sessions on AE reporting revealed much confusion about AE's, especially differing terminology used by the Food and Drug Administration (FDA) and IRB regulations. The bottom line was that IRB's need to identify terms that work for them and use them consistently. Several sessions were devoted to improving the informed consent process. It was noted that some subjects rely very heavily on what their physicians tell them and do not want to be informed in detail about the risks of research. The question was raised whether we are really respecting autonomy when we require adherence to an informed consent process when this is not what the subject wants.

Several exhibits demonstrated web-based training opportunities in human subjects protection and one exhibit show-cased software for developing consent forms (Consent Form Wizard, Traversent LLC). The software is designed to help researchers create consent forms by leading them through interactive step-by-step instructions on the web. An online demo can be accessed at http://www.traversent.com/consent.

Summary

The RCQ staff found many of the sessions to be very informative, and networking opportunities for discussing best practices and ethical issues with other IRB's were particularly valuable. Additional information about the meetings can be obtained from the conference proceedings. We encourage attendance at these types of meetings by IRB members, support staff, and study personnel as part of their continuing education. Additional information about PRIM&R and ARENA can be obtained at http://www.primr.org.

FOLLOW-UP ARTICLE: "UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS AND OTHERS"

The Human Subjects Research Review Board (HSRRB) clause for reporting unanticipated problems was recently updated. The information that follows provides guidance to investigators regarding what is required when reporting adverse events (AEs) and unanticipated problems to the HSRRB. Please note that the clause provided below should be used in any new protocols submitted to the HSRRB for review. For those protocols that include the old reporting information, investigators may continue to report as per the requirements of the old clause. Alternately, an amendment request can be submitted to the HSRRB requesting that the protocol be revised to incorporate the new clause.

The Human Subjects Protection (HSP) Regulations at 32 Code of Federal Regulation (CFR) 219 and 45 CFR 46 require that Institutional Review Boards (IRBs) have written procedures for ensuring prompt reporting to the IRB, institutional officials, and

the department or agency head any unanticipated problems resulting in risks to subjects or others. IRBs are responsible for determining what is meant by "prompt," developing an appropriate reporting procedure, and communicating this procedure to those engaged in research within the IRB's purview. Reporting procedures will differ from institution to institution, so it is important for investigators to identify the reporting requirements for all entities involved in review of the protocol and to clearly define this procedure within the protocol. The HSRRB has outlined its procedure in HSRRB Policy Memorandum 02-01, Reporting to the HSRRB Unanticipated Problems Involving Risks to Subjects and Others which can be found on the Human Subjects Protection page of the Regulatory Compliance and Quality (RCQ) website. Reports submitted to the HSRRB fulfill the requirement of notification of the department or agency.

HSRRB Policy Memorandum 02-01 can be found on the HSP page of the RCQ website at mrmc.detrick.army.mil

What is meant by any unanticipated problems resulting in risks to subjects or others? This statement encompasses more that what one usually thinks of as adverse events. "Problems involving risk" may not necessarily result in harm. For example, misplacing a subject's study records containing identifiable private information results in the risk of breach of confidentiality. Confidentiality may or may not be breached, but either way this would be a reportable event. Another example would be administering the wrong agent to a subject at one time point in a series of vaccinations. Risks to others must also be reported. For example, an inadvertent exposure of a household contact in a smallpox vaccine trial would be a reportable event. Problems resulting in risks to members of the research team are also reportable.

Unanticipated problems are those problems that are not described in the protocol or other study documents. The HSRRB policy provides a sample reporting form that includes all of the elements required to be reported. Investigators may use this form if there is no equivalent available at their local institution. If the institutional form or study-specific form does not contain all of the elements contained on the HSRRB reporting form, additional information may be requested from the investigator by the Human Subjects Protection (HSP) staff. For studies with a medical monitor assigned, the investigator must inform the medical monitor of any adverse events. A medical monitor report that comments on the outcomes of the event and the relationship of the event to participation in the study must be submitted to the HSRRB within ten calendar days. The medical monitor should indicate whether he/she concurs with the details provided in the investigator's report. Follow-up reports should be submitted until resolution of the unanticipated problem. Appropriate supporting documents, such as laboratory reports, pathology reports, and discharge summaries should be submitted with the unanticipated problem report.

The HSRRB requires that the following language appear in all protocols:

"Unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and all subject deaths should be promptly reported by phone (301-619-2165), by email (hsrrb@det.amedd.army.mil), or by facsimile (301-619-7803) to the Army Surgeon General's Human Subjects Research Review Board. A complete written report should follow the initial telephone call. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-ZB-QH, 504 Scott Street, Fort Detrick, Maryland 21702-5012".

Protocols with a medical monitor assigned should also include the following information:

"The medical monitor is required to review all unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and all subject deaths associated with the protocol and provide an unbiased written report of the event. At a minimum, the medical monitor should comment on the outcomes of the event or problem, and in the case of an adverse event or death, comment on the relationship to participation in the study. The medical monitor should also indicate whether he/she concurs with the details of the report provided by the study investigator."

RA

REGULATORY AFFAIRS UPDATES

REGULATORY AFFAIRS CERTIFICATION FOR MS. KATHIE MANTINE

Kathie Mantine, the veteran of RCQ Regulatory Affairs earned the Regulatory Affairs Certification (RAC) distinction in April 2004.

The RAC is awarded on performance on a comprehensive examination testing knowledge of FDA and related US laws, regulations, policies and guidelines, emphasizing drugs, medical devices and biologics. The RAC designation is a mark of professional distinction identifying individuals committed to excellent, career advancement and pursuit of knowledge.

The certification program is designed to elevate professional standards, distinguish individuals demonstrating knowledge essential to regulatory affairs, and enhance individual performance. Current RACs are among the current and rising leaders in regulatory affairs and related health industries.

Major General Martinez-Lopez
Kathie Mantine, Regulatory Affairs Scientist

We are certainly proud of Kathie's achievements and appreciate the effort she took to earn this honor. Congratulations Kathie!

WHAT IS A 510(K) APPLICATION? WHEN DO I NEED TO SUBMIT ONE?

This short introduction to the world of Medical Devices is intended to introduce some of the key terms that are used for regulation of medical devices. This article introduces terms associated with the 510(k) application. Future editions will describe other medical device applications.

A 510(k) must be submitted and cleared by the Food and Drug Administration (FDA) prior to the marketing of a medical device in humans. As we break down this sentence, the first question we may have is… What is a Medical Device? The Federal Food Drug and Cosmetic Act defines a Medical Device as "…an instrument, apparatus, implement, machine, contrivance, implant, or in vitro reagent…which is (1) intended for use in the diagnosis of disease, or in the cure, mitigation, treatment or prevention of disease, or (2) intended to affect the structure or function of the body…."

From the definition, we can see that medical devices can span a great range. Everything from cardiac pacemakers and coronary stents on the significant risk end to thermometers, wheelchairs, and hospital beds on low risk end of the spectrum.

A 510(k) must be submitted and cleared by the FDA prior to the marketing of a medical device in humans.

Also from the definition, we can see it is not always easy to determine if a device is a *medical* device. For example, when is a bed just a bed and when is it a medical device. The *intended use* of the device determines when it crosses over to *medical* device. The intended use is determined from the labeling, promotional materials, and even the advertising. For example, a bed that was labeled and promoted as having special

(Continued on page 6)

(Continued from page 5)

features to make it especially suitable for use in a hospital or for use by sick people may be a medical device. The FDA always looks at the intended use of a device to determine if it is a medical device.

Using the idea of intended use, the FDA has classified medical devices into three classes based on their risk.

- Class I (Low Risk)
  - ✓ Examples are manual surgical instruments, wheelchairs, tongue depressors
  - ✓ Exempt from 510(k) requirements
  - ✓ General controls alone are adequate to insure safety

- Class II (Medium Risk)
  - ✓ Examples are many clinical chemistry tests, clinical toxicology tests
  - ✓ 510(k) required
  - ✓ Special controls such as performance standards are needed in the manufacturing

- Class III (Significant Risk)
  - ✓ Examples are kidney dialysis machines, laser eye surgery equipment
  - ✓ PMA required to be submitted and approved
  - ✓ Special controls and clinical studies are required for approval

The Code of Federal Regulations (21 CFR 807) gives the requirements for a 510(k) submission. The 510(k) submission is required to demonstrate that the new device is *substantially equivalent* to a currently marketed device.

The substantial equivalence is based on identifying a *predicate* device that has the same *intended use* and either the same *technological characteristics*, or, if the technological characteristics are different, the technological characteristics do not introduce new questions about the safety and effectiveness of the device.

These technical terms such as substantial equivalence, predicate device, intended use, and technological characteristics, all have legal definitions. However, the key question is how are they interpreted in practice? Intended use is generally interpreted pretty broadly, that is, two devices that have different uses may be deemed to have the same intended use. For example, a comparison of two diagnostic devices may conclude that they have the same intended use even when they are used to diagnose two different diseases. In this case, the two devices can have the same intended use but different technological characteristics. The new device could be substantially equivalent to the original device based on meeting performance standards. When your device is *substantially equivalent* to an existing device, it is said to *cleared* (similar to *approved*).

For questions about when 510(k) submissions are required and how to go about putting together a submission, call Richard Potter, Amdex Corporation, in Regulatory Compliance and Quality, Regulatory Affairs, 301-619-6241, or anyone else in the Regulatory Affairs branch.

QA

QUALITY ASSURANCE UPDATES

YOU THINK YOU KNOW AN AUDIT?

Prior to beginning any discussion on how an audit is planned, conducted and completed, it is necessary to start with the definition of "audit". Depending on the context of the organization, an audit can mean different things to different people. For example, if you are

(Continued on page 7)

(Continued from page 6)

in the accounting business, an audit would be considered a review of financial ledgers or accounting procedures. The Army definition of "audit", found in Army Regulation (AR) 1-201 is, "The independent appraisal activity within the Army for the review of financial accounting, and other operations, as basis for protective and constructive service to command and management at all levels." In the regulated clinical setting, the International Conference on Harmonization, Good Clinical Practices (E6), an audit is defined as; "A systematic and independent examination of trial related activities and the documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP) and the applicable regulatory requirements."

To further complicate understanding of the word "audit", if "Quality" is added as an adverb (or pronoun), than the definition is modified. For example, the Army defines "Quality Audit" in AR 1-201 as, "A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve the objectives." In the regulated area of device manufacturing (21 CFR Part 820.3(t)), a Quality Audit is defined as, "A systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality systems activities and the results of such activities comply with quality system procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives."

Review of the definitions presented shows a common theme to each and there are 2 take home messages from this definitional review. The first message is that an audit, regardless of the type, is the independent examination of whatever is audited and the second message is to be very clear in defining and understanding the objective of the audit.

There are normally four phases to an audit, the initiation and preparation phase, the performance phase, the reporting phase and the closure phase.

The first phase, initiation and preparation, is where audit objectives are defined, scope is established, resources are allocated, site personnel contacted, checklists developed, historical review of previous audits, and an understanding of the site's process and control systems has occurred. Results include: audit plan, checklist, an initial evaluation based on historical data and past performance and a plan of action for areas needing verification during the on-site phase of the audit.

There are normally four phases to an audit, the initiation and preparation phase, the performance phase, the reporting phase and the closure phase.

The second phase, performance, is the actual fieldwork. It is the data- gathering portion of the audit and begins with an opening meeting. The purpose of the opening meeting is to introduce the team members and staff being visited, circulate an attendance roster, establish communication links, clarify the audit plan with all those concerned, confirm logistics and confirm a date and time for the closing meeting. The data gathering process then occurs and takes the bulk of the scheduled time, factual information is gathered and evaluated against standards or requirements, conclusions are drawn and the results reported to management. A closing meeting ends the performance stage of the site visit. At the closing meeting, the lead auditor should present verbal or written draft or preliminary findings to the audited site.

The third phase, reporting is the formal communication of the audit results in a written report. It is prepared, signed and dated by the lead auditor.

The final phase, closure involves closing all observations after corrective action has been received, accepted and verified. The audited organization is formally notified of observation closure.

After all that work, the audited site should now be prepared for an inspection. But that will be saved for a later date!

ACURO Animal Care Use & Review Updates

New Additions to the ACURO Team

Ms. Nina Cisar has joined MRMC-RCQ as an Animal Use Review Specialist. She comes to us from the National Institutes of Health (NIH) where she worked as the animal program coordinator and Institutional Animal Care and Use Committee (IACUC) Administrator for the National Institute for Mental Health (NIMH). She has over ten years experience in the laboratory animal and protocol management field. She was employed as an IACUC Support Assistant at the Uniformed Services University of the Health Sciences before her position at NIMH.

Ms. Cisar will be part of the Animal Care and Use Review Office (ACURO) team which is responsible for reviewing all animal use proposals in USAMRMC and CDMRP extramural research projects. ACURO advises USAMRMC on issues regarding laboratory animal medicine and ensures that all animal care and use within USAMRMC is conducted in compliance with animal welfare policies and regulations.

Lieutenant Colonel Vincent Gresham will join the ACURO team in October as the Deputy Director of the Animal Care and Use Review Office. He is a Diplomate in the American College of Laboratory Animal Medicine and the American College of Veterinary Preventive Medicine. He received his DVM from Texas A&M and his Master of Science Degree in Comparative Medicine from Pennsylvania State University. His prior laboratory assignments include: US Army Medical Research Institute for Chemical Defense, Walter Reed Army Institute for Research, Brooke Army Medical Center, Clinical Investigations Regulatory Office (Fort Sam Houston), and the Air Force Research Laboratory (Brooks Air Force Base). His research interests focus on animal model refinements for animal studies addressing toxicologic diseases. His ACURO duties will include review of laboratory animal use proposals, site visits to DOD contracted research laboratories, and special projects for the Command. LTC Gresham can be reached at (301) 619-6094 and Vincent.Gresham@amedd.army.mil.

Veterinary Activities in CBRNE Biomedical Research Short Course

While overall the second quarter of 2004 was one of intense activity within the ACURO, the tempo slowed down the third week of April to host the annual Veterinary Activities in Chemical, Biological, Radiation, Nuclear, and Explosives (CBRNE) Biomedical Research Short Course. The short course was funded by the U.S. Army Veterinary Corps and hosted by the Animal Care and Use Review Office. This three-day training event was again held at the American Inn, Bethesda, MD where for three days a dozen junior Veterinary Corps Officers were introduced, at least peripherally, to the workings of the U.S. Army Medical Research Institute of Chemical Defense (USAMRICD), U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and Armed Forces Institute of Pathology (AFIP). This course is offered to 0-3 level Veterinary Corps officers as an opportunity to introduce them to the myriad of opportunities that await them should they choose the biomedical research field as their career path in the Army. The course was a terrific success as verified by the feedback received from the participants and hosts. Next year we hope to increase the course by an additional day so the Walter Reed Army Institute of Research (WRAIR) can be added as a fourth site for the short course. Many of the individuals who attended requested a visit to the WRAIR be added to the short course in their after action critiques. Congratulations to all responsible for making this such successful and meaningful training.

FY03 DATA CALL ON THE USE OF LABORATORY ANIMALS IN DOD

The next major mission for ACURO beginning approximately mid-June is managing the FY03 Data Call on the Use of Animals in the DoD for USAMRMC's extramural researchers. This Congressional mandate requires the collection of information regarding types of animal research and the number of animals used in DoD research. This information helps the DOD and ACURO respond to public and Congressional inquiries regarding the use of animals involved in research. The ACURO will receive all the requested information from extramural researchers sponsored by USAMRMC, the Congressionally Directed Medical Research Program and the Defense Advanced Research Projects Agency. The ACURO will then filter and format the data for the final report DOD Report. This effort ensures the integrity of the data collected and will continue for a few months after the data call closes on August 31. Ms. Barbara Stone, x-33776 and Ms. Lisa Fucci-Baker, x-36096 are our respective points of contact for MRMC and DARPA Data Call inquiries.

RCQ HAILS AND FAREWELLS

The Office of Regulatory Compliance and Quality (RCQ) would like to extend warm welcomes to three new members of our staff. They are Ms. Nina Cisar, Ms. Debra DePaul, and Major Mallory Tate. Furthermore, we would like to congratulate Mr. Tibor Tuzson for accepting the position of Human Subjects Protection (HSP) and Regulatory Liaison Scientist.

Ms. Nina Cisar joined the Animal Care Use and Review Office (ACURO) branch of RCQ as an Animal Use Review Specialist. Nina brings with her over 10 years of experience in the laboratory animal and protocol management field. Previously, she worked at the National Institutes of Health (NIH) as the animal program coordinator and Institutional Animal Care and Use Committee (IACUC) Administrator for the National Institute for Mental Health (NIMH). In RCQ, Nina is responsible for reviewing all animal use proposals in USAMRMC and Congressionally Directed Medical Research Program (CDMRP) extramural research projects. Nina can be reached at 301-619-6064 or Nina.Cisar@det.amedd.army.mil.

(Continued on page 10)

AROUND THE COMMAND

COL Coleen Martinez, Deputy Commander for the U.S. Army Medical Materiel Development Activity (USAMMDA), was awarded a Bronze Star Medal. She received this honor for her exceptional work in developing Post Deployment Health Assessment (PDHA) programs in Kuwait and Iraq.

Congratulations to Dr. Kent Kester, Director of the Department of Clinical Trials at Walter Reed Army Institute of Research (WRAIR) and Human Subjects Research Review Board (HSRRB) member, on his promotion from Lieutenant Colonel to Colonel on the 18th of June.

The U.S. Army Medical Materiel Center, Europe (USAMMCE) was recertified by the Technical Inspection Institute (TUEV CERT, Certification Body for Quality Management Systems), for the ISO 9001:2000 based Quality Management System in June 2004. This certification is valid from June 2004 through June 2007. During the past year USAMMCE has improved over 20 processes and implemented 17 new ones all contributing to the overall quality and continuous improvement process within their organization. Congratulations to all of the staff at USAMMCE for their continuous improvement efforts!

RCQ **REVIEW**

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(Continued from page 9)

Ms. Debra DePaul joined RCQ in April of 2004 as a HSP Review Scientist. Debra has over 20 years of experience in the medical arena. Previously, she worked at Palladian Partners, Incorporated, located in Silver Spring, as a Program Manager. Here Debra was responsible for daily implementation of pre- and post-award grant management activities. In RCQ, Debra is reviewing protocols and providing informal and formal guidance to PIs on behalf of the Acting Chair of the HSRRB. Debra can be reached at 301-619-2620 or Debra.DePaul@det.amedd.army.mil.

Lieutenant Colonel Vincent Gresham will join RCQ in October as the Deputy Director of ACURO. LTC Gresham's most recent assignment was at the Medina Veterinary Clinic supporting the DOD Military Working Dog Training Center in San Antonio, Texas. He is a Diplomate in the American College of Laboratory Animal Medicine and the American College of Veterinary Preventive Medicine, and has over 12 years of experience in the military laboratory animal medicine field. LTC Gresham can be reached at 301-619-6094.

Mr. Tibor Tuzson, previously a HSP Scientist, has accepted the position of HSP and Regulatory Liaison Scientist. In addition to the ethical review of research protocols, Tibor is now responsible for coordinating between MRMC and the Joint Vaccine Acquisition Program-Project Management Office (JVAP-PMO) to ensure that all applicable regulatory compliance requirements are met for products developed through the JVAP. Tibor can be reached at 301-619-6192 or Tiberiu.Tuzson@det.amedd.army.mil.

Unfortunately, the RCQ family has lost four member of our team. We would like to say farewell to Ms. Maya Laws and Ms. Shannon Lertora, both Office Automation Clerks and co-editors of the RCQ Review. In addition, we would like to say farewell to Ms. Bonnie Bloomquist our Training Program Leader and MAJ Mallory Tate our Deputy Director of ACURO. RCQ wishes them the best of luck in their future endeavors. They will be missed dearly.

HELPFUL LINKS

- US Army Center for Health Promotion & Preventive Medicine http://chppm-www.apgea.army.mil/
- NIH Guidance on Informed Consent for Gene Transfer Research http://www4.od.nih.gov/oba/rac/ic
- Info for Conducting International Research http://www.cioms.ch/frame_guidelines_nov_2002.htm
- HSRRB Policy Memorandum 02-01 https://mrmc.detrick.army.mil/docs/rcq/HSRRB0201.pdf
- Army Regulation 1-201 Army Inspection Policy http://www.usapa.army.mil/pdffiles/r1_201.pdf
- The Belmont Report https://mrmc.detrick.army.mil/docs/rcq/belmont.pdf